DEVELOPMENT OF A HIGH DENSITY PERCUTANEOUS CONNECTOR SYSTEM

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Abstract

This report summarizes activity over the period from July 15, 1999 through October 15, 1999 on NIH Contract N01-DC-7-2103, "Development of a High Density Percutaneous Connector System". During this quarter the final implants have started, fabrication of a quick disconnect design has started and leakage problems have been solved.

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I. Background and Review of Contract Requirements

This report summarizes activity during the specified quarter, on NIH Contract N01-DC--2103, "Development of a High Density Percutaneous Connector System". Over the course of this contract, a high density, planar, low profile connector system is being developed that incorporates pad grid array technology. This technology has unique advantages as applied to a

percutaneous interconnect system. In particular the connector system will be low in profile, easy to clean, sealed against ingress of contaminants, offer low mechanical resistance to mating and demating and provide a very high number of contacts in a small diameter. The connector system will be implanted in a suitable animal model and the appropriate electrical, mechanical, and biocompatible properties of the system will be assessed. The specific technical requirements of this connector system as detailed in the contract are explained below:

- The connector will incorporate a pedestal that can be attached to the skull in a mechanically stable manner. The pedestal will be designed to accept a replaceable connector assembly. All materials of the pedestal in contact with tissue will be biocompatible and the profile of the pedestal will be low enough to minimize any physical trauma during mating and demating of the connector or due to normal physical activities.

- The connector assembly will be high-density with at least 70 contacts. The electrical isolation between the contacts or between the contacts and the body should withstand at least 18 volts without breakdown. The connector contacts when mated should be capable of passing up to 20 mA of current with less than a 1.0 volt drop across the connection. A simple method of mating and demating the upper and lower surfaces of the connector should be provided. In addition, a convenient means to attach electrical leads to the connector is needed.

- The connector will be designed from materials that are durable and can withstand the physical abuse from normal activities of daily living. The interface between the connector and the skin must be such that the passage of microorganisms into the body and fluid drainage out of the body is prevented.

- In earlier studies connectors had five separate loops of insulated wire, each 2 inches long. Because of wire breakage observed during these studies, it is necessary to make a more durable and a more realistic part. The present cable is a ribbon one-inch long with five 2-mil Pt/Ir wires, coated with Parylene and Silicone. The wires are looped so there are five loops for testing. The 2 mil wires are more rugged and easier to work with for initial tests, but 1 mil wires will be used after the ribbon cable concept is developed. An 18-Volt bias will be maintained on the wires relative to an implanted platinum wire connected to one of the unused contacts or the Ti connector body. The leakage current of the cable wires will be monitored with a maximum acceptable value of 10 nanoamperes.

- Performance of the connector system will be tested in a suitable animal model. After three to six months of implantation, the connector assembly will be explanted and gross and microscopic examinations will be performed to study the attachment of the pedestal to the skull, the attachment of the skin and soft tissue surrounding the pedestal to the pedestal wall and the reaction of adjacent tissue to the implanted device.

- Finally, design changes and improvements, if needed, will be recommended. A set of connectors will be fabricated and sent to the NIH for implantation. Initial testing will be in cats with final tests conducted in non-human primates.

II. HMRI Work

HMRI has started implanting the final six deliverables. These are two stage surgeries in which the pedestal is implanted and allowed to osseointegrate prior to connection of the percutaneous stage.

III. Leakage Problems

In the last QPR the results of an almost year long study of leakage problems was reported. Leakage had been reduced, but was still not acceptable. This is in a design that has been used successfully (< 1 nA leakage) for a number of years. The leakage was occurring between pieces of Alumna used for pin alignment in the lower PGA element. The upper (external) mating PGA element has the same construction, but does not show leakage because it is not exposed to moisture and ions. The source of both moisture and ions is diffusion through polymers – both silicones and epoxy. The cause of leakage is voids in epoxy between the Alumna pieces.

It was determined that the two-piece Alumna structure would not be used in the lower or first connector section because there is no way to insure complete filling of the space between the Alumna pieces. For final deliverables in this contract two structures will be used. The first is a solid core of a modified EpoTek 301, the same material used for some years. The second is Alumna on the top surface backed by modified EpoTek 301 for strength.

EpoTek 301 "slabs" were built approximately 130 mils thick. These were laser machined at Applied Laser Technology (ALT). Early work showed this to be viable with only minor discoloring on the machined surfaces. However, when more complete pieces were machined the discoloring penetrated the bulk of the material and leakage tests showed the method was not suitable. Mechanical machining methods had not been considered because of cost considerations, but this was now the only option. Mechanically machined modified EpoTek 301 pieces have been fabricated and are being tested. Leakage remains less than 20 pA between adjacent PtIr pins. Also, it has been found that the cost is comparable to the laser machined parts and is no longer an issue.

Cleaning at several steps during the fabrication and clean methods (gloves, mask and clean tools and surfaces) have continued to be used during the present work. Work is done in a normal room environment with caution to avoid dirty conditions such as work near a high traffic area. Figure 1 below shows a typical leakage test. The initial readings are a slow meter run-in. After that the slope seems to be a surface moisture phenomena, which settles to less than a picoAmp after an hour. Tests will continue until the material starts to degrade.

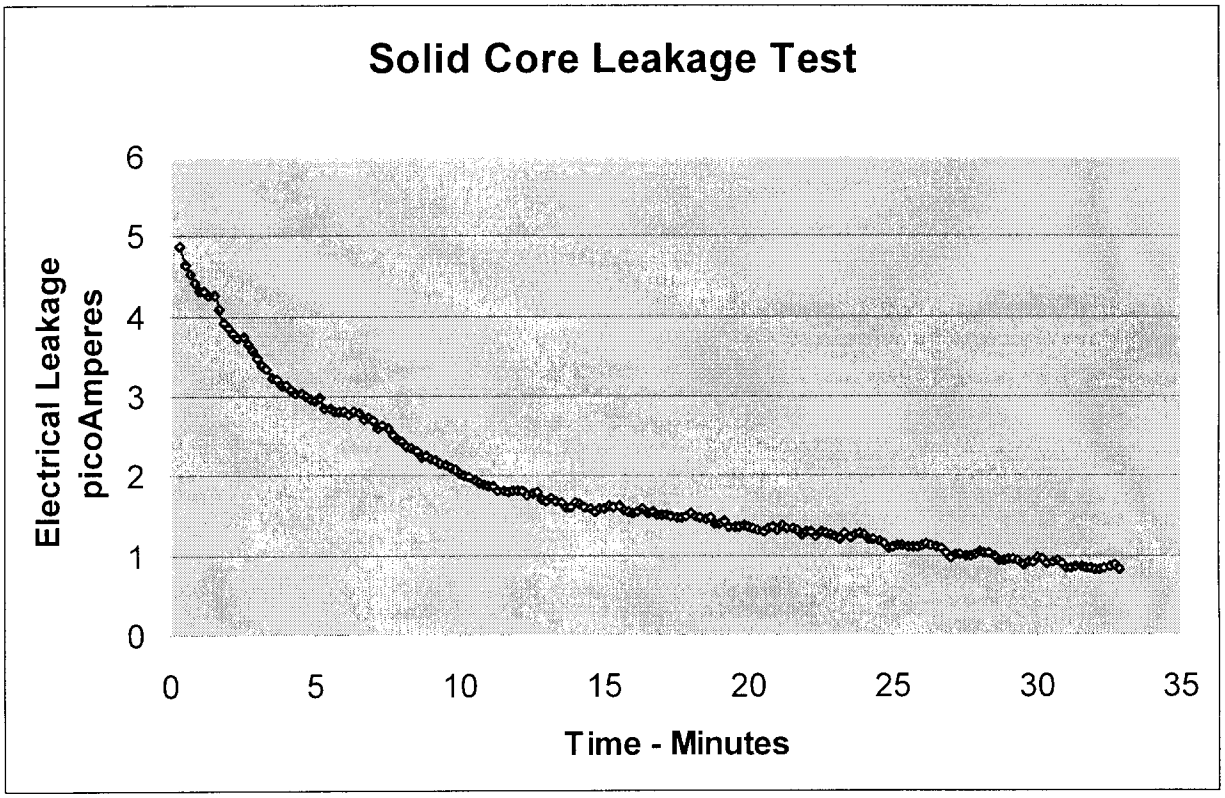

Figure 1. Modified EpoTek 301 Solid Core Leakage Test.

The solid core epoxy described above is not considered a long term implant. Although the modified EpoTek 301 is a good long-term material, there are probably better polymers, some of which are being tested. However, the best solution would be a solid ceramic core. This was tried and reported in earlier QPRs. The effort was abandoned because of difficulties in making the ceramic performs and incomplete firing of the material. However, a ceramic material remains the best option for long-term implants. Two of the six final deliverables will have ceramic (Alumna) surfaces with EpoTek 301 fill back of the Alumna for strength since the Alumna pieces will be only 30 mils thick. This is considered only a step toward a more permanent design. A complete solid core remains the goal with a ceramic surface backed by high durometer, long-term polymer, a second choice.

IV. Investigation into Other Pin Matrix Materials

Testing of polymer materials for use in long term implants continues. No additional significant results are available this quarter.

V. Skin Growth and Attachment

As was reported at the NINDS conference, the beaded skin attachment surface seems the best available, but more extensive work is needed for a conclusive demonstration.

Laminin-5 reported earlier as having no infection and no attachment has proved to have good attachment from histology reports (presented by HMRI at NINDS). The Laminin-5 work has been very limited, but more encouraging than when first reported.

Two dummy connectors with beaded surfaces for skin attachment were implanted during this quarter. This is at the suggestion of Dr. David Edell because even implants with good skin healing and attachment seem to fail sometime after three months. These will remain implanted for at least four months. One experiment that started as an electrostimulation study last winter remains successfully implanted.

VI. Quick Disconnect

The quick disconnect (QD) design has been completed. Analysis of the structure for strength and durability continues. The first pieces of the design have been ordered with the remainder to follow within two weeks. No implant of a QD design is expected, but one complete unit will be delivered to NIH.

VII. Primate Studies

There has been no change in the intention to complete three primate implants. We are waiting on our sister project to complete work necessary for the implants to progress.

VIII. Manufacturing Methods

The problem with the sintered titanium bead reported last quarter remains, but a partial fix has been found. The parts to be beaded are machined with a large mass of material attached. This thermal mass seems to improve the bead structure. At least two other vendors capable of beading Titanium are known, but at this late date in the project it is not feasible to make the vendor change.

IX. Activities for the Ninth Quarter

During the next quarter:

- Finish the initial Quick Disconnect design and initial fabrication
- Continue the accelerated life testing of polymers
- Complete the long-term skin implant experiments
- Complete tests on final deliverables
    - Solid Core – Low Leakage design with cable
    - Ceramic surface – Low Leakage design with cable